

Medical Policy



Title: Balloon Sinuplasty for Treatment of Chronic Sinusitis

Professional

Original Effective Date: November 10, 2006
 Revision Date(s): February 16, 2011;
 August 1, 2011; September 21, 2011;
 September 24, 2012; November 11, 2016;
 July 1, 2017; January 1, 2018;
 March 14, 2018; March 27, 2019
 Current Effective Date: November 11, 2016

Institutional

Original Effective Date: January 14, 2009
 Revision Date(s): February 16, 2011,
 August 1, 2011; September 21, 2011;
 September 24, 2012; November 11, 2016;
 July 1, 2017; January 1, 2018;
 March 14, 2018; March 27, 2019
 Current Effective Date: November 11, 2016

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

Populations	Interventions	Comparators	Outcomes
Individuals: • With chronic rhinosinusitis	Interventions of interest are: • Balloon ostial dilation as a stand-alone procedure	Comparators of interest are: • Medical management • Functional endoscopic sinus surgery	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With chronic rhinosinusitis	Interventions of interest are: • Balloon ostial dilation as an adjunct to functional endoscopic sinus surgery	Comparators of interest are: • Functional endoscopic sinus surgery alone	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity

DESCRIPTION

Balloon ostial dilation (also known as balloon sinuplasty) is proposed as an alternative to traditional endoscopic sinus surgery for patients with chronic rhinosinusitis who fail medical management. The procedure involves placing a balloon in the sinus ostium and inflating the balloon to stretch the opening. It can be performed as a stand-alone procedure or as an adjunctive procedure to functional endoscopic sinus surgery (FESS).

OBJECTIVE

The objective of this policy is to evaluate whether balloon ostial dilation improves the net health outcome for patients with chronic rhinosinusitis.

BACKGROUND**Chronic Rhinosinusitis**

Chronic rhinosinusitis (CRS) is characterized by purulent nasal discharge, usually without fever, that persists for weeks to months. Symptoms of congestion often accompany the nasal discharge. There also may be mild pain and/or headache. Thickening of mucosa may restrict or close natural openings between sinus cavities and the nasal fossae, although symptoms vary considerably because of the location and shape of these sinus ostia.

Treatment

Estimates are that approximately 30 million individuals in the United States suffer from chronic rhinosinusitis. Most cases are treated with medical therapy, but surgical drainage is an option for patients who fail to respond to medical therapy. FESS has become an important aspect for surgical management of chronic sinusitis, although evidence from randomized controlled trials (RCTs) is limited. For this procedure, a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. This procedure restores patency and allows air and mucous transport through the natural ostium. Approximately 350,000 FESS procedures are done each year in the United States for CRS.

A newer procedure, balloon ostial dilatation, can be used as an alternative to FESS or as an adjunct to FESS for those with chronic rhinosinusitis. The goal of this technique, when used as an alternative to FESS, is to achieve improved sinus drainage using a less invasive approach. When used as an adjunct to FESS, it is intended to facilitate and/or increase access to the sinuses. The procedure involves placing a guidewire in the sinus ostium, advancing a balloon over the guidewire, and then stretching the opening by inflating the balloon. The guidewire location is confirmed with fluoroscopy or with direct transillumination of the targeted sinus cavity. General anesthesia may be needed for this procedure to minimize patient movement.

The maxillary sinus creates a unique challenge. The maxillary ostia, located within the ethmoid infundibulum, often cannot be accessed transnasally without excising a portion of the uncinat process. An alternate approach to the maxillary ostia is through the sinus,

via the canine fossa. A guidewire can be advanced from within the maxillary sinus to the nasal fossa. The dilating balloon can enlarge the ostia while deflecting the uncinat process.

Outcomes

To quantify the severity of chronic rhinosinusitis and to assess treatment response, various outcomes measures can be used, including patient-reported quality of life (QOL) measures, radiologic scores, and endoscopic grading.

The Lund-McKay scoring system utilizes radiologist-rated information derived from computed tomography scans regarding opacification of the sinus cavities, generating a score from 0 to 12.^{1,2}

Several disease-specific patient-reported QOL scores have been used. Commonly used is the Sino-Nasal Outcome Test–20 (SNOT-20), which is a validated questionnaire for which patients complete 20 symptom questions on a categorical scale (0 [no bother] to 5 [worst symptoms can be]). Average rankings can be reported over all 20 symptoms, as well as by 4 subclassified symptom domains. The SNOT-22, variation of the SNOT-20, includes 2 additional questions (“nasal obstruction” and “loss of smell and taste”). The minimal clinically important difference for the SNOT-22 has been estimated to be 8.9 points.³

Additionally, QOL may be reported based on overall health-related QOL scores, such as the 36-Item Short-Form Health Survey-36 (SF-36). The SF-36 includes 8 scaled scores on various health domains, which are transformed into a 0-to-100 scale (100 corresponding to best health).

REGULATORY STATUS

In March 2008, the Relieva™ Sinus Balloon Catheter (Acclarent, Menlo Park, CA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for use in dilating the sinus ostia and paranasal spaces in adults and maxillary sinus spaces in children. Subsequent devices developed by Acclarent have also been cleared by FDA through the 510(k) process. These include the Relieva Spin Sinus Dilation System® cleared in August 2011 and the Relieva Seeker Balloon Sinuplasty System® cleared in November 2012.

In June 2008, the FinESS™ Sinus Treatment (Entellus Medical, Maple Grove, MN) was cleared for marketing by FDA through the 510(k) process. The indication noted is to access and treat the maxillary ostia/ethmoid infundibulum in adults using a transantral approach (FDA product code: EOB). The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures. Two other balloon sinus ostial dilation devices, the ENTrigue® Sinus Dilation System (ENTrigue Surgical, subsequently acquired by ArthroCare, Austin, TX, acquired by Smith and Nephew, London,

UK), and the XprESS™ Multi-Sinus Dilation Tool, also received 510(k) clearance in August 2012.

In 2013, a sinus dilation system (Medtronic Xomed, Jacksonville, FL), later named the NuVent™ EM Balloon Sinus Dilation System, was cleared for marketing by the FDA through the 510(k) process for use in conjunction with a Medtronic computer-assisted surgery system when surgical navigation or image-guided surgery may be necessary to locate and move tissue, bone, or cartilaginous tissue surrounding the drainage pathways of the frontal, maxillary, or sphenoid sinuses.

Also in 2013, a sinus dilation system (ArthroCare, San Antonio, TX, a division of Smith and Nephew), later named the Ventera™ Sinus Dilation System, was cleared for marketing through the 510(k) process to access and treat the frontal recesses, sphenoid sinus ostia, and maxillary ostia/ethmoid infundibula in adults using a transnasal approach.

Table 1 summarizes the currently FDA-cleared balloon sinus dilation devices.

Table 1. Balloon Ostial Dilation Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	510(k) No.	Date Cleared	Indication
MESIRE - Balloon Sinus Dilatation System	Meril Life Sciences	K172737	12/12/2017	Sinus Ostia Dilation
Relieva SpinPlus Nav Balloon Sinuplasty System	Acclarent Inc.	K171687	9/5/2017	Sinus Ostia Dilation
XprESS ENT Dilation System	Entellus Medical Inc.	K163509	4/5/2017	Sinus Ostia Dilation
Relieva UltirraNav Sinus Balloon Catheter	Acclarent Inc.	K161698	10/24/2016	Sinus Ostia Dilation
Vent-Os Sinus Dilation Family	Sinusys Corp.	K160770	6/29/2016	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K153341	2/12/2016	Sinus Ostia Dilation
XprESS Multi-Sinus Dilation System	Entellus Medical Inc.	K152434	11/20/2015	Sinus Ostia Dilation
DSS Sinusplasty Balloon Catheter	Intuit Medical Products LLC	K143738	8/27/2015	Sinus Ostia Dilation
Relieva SpinPlus Balloon Sinuplasty System	Acclarent Inc.	K143541	4/22/2015	Sinus Ostia Dilation
XprESS Multi-Sinus Dilation Tool	Entellus Medical Inc.	K142252	10/17/2014	Sinus Ostia Dilation
Relieva Scout Multi-Sinus Dilation System	Acclarent Inc.	K140160	2/20/2014	Sinus Ostia Dilation

FDA product code: LRC

POLICY

- A. Balloon sinus ostial dilation is considered **medically necessary** for treating rhinosinusitis lasting longer than 12 weeks or 4 or more documented episodes of acute rhinosinusitis (in one year) when **ALL** of the following are met:
1. Confirmation with computed tomography (CT) scan and/or nasal endoscopy of findings of rhinosinusitis that includes one or more of the following:
 - a) Nasal endoscopy showing purulent discharge or persistent inflammatory sinus pathology, **OR**
 - b) CT evidence of mucosal thickening, bony remodeling, bony thickening, or obstruction of the ostiomeatal complex; **AND**
 2. Balloon sinus ostial dilation is limited to the frontal, maxillary or sphenoid sinuses; **AND**
 3. Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS); **AND**
 4. Balloon sinus ostial dilation is performed on patients whose symptoms persist despite maximal medical therapy (see Policy Guidelines).
- B. Balloon ostial dilation is considered **not medically necessary** in the following situations:
1. Nasal polyposis (Grade 2 or greater);
 2. Samter's triad (aspirin sensitivity);
 3. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, Wegener's granulomatosis);
 4. Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis;
 5. Contraindication to, or inability to tolerate local and/or topical anesthetic;
 6. History of failed balloon procedure in the sinus to be treated;
 7. Sinusitis with extensive fungal disease;
 8. Isolated ethmoid sinus disease;
 9. Significant neo-osteogenesis.

- C. Balloon sinus ostial dilation for treatment of chronic sinusitis is considered **experimental / investigational** for any other indication.

Policy Guidelines

1. There are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site.
2. When a balloon sinuplasty is used as an adjunct in performance of a medically necessary functional endoscopic sinus surgery (FESS) in the treatment of chronic sinusitis, the use of the balloon catheter is considered included in the allowance for the FESS procedure. There is no additional reimbursement for use of the balloon catheter.
3. If balloon sinuplasty is performed in conjunction with cutting tools such as curettes and forceps, the procedure might be coded using the CPT codes for nasal/sinus endoscopy with maxillary antrostomy (31256), nasal/sinus endoscopy with frontal sinus exploration (31276), or nasal/sinus endoscopy with sphenoidectomy (31287). In this instance, the balloon dilation would be considered inclusive/incidental to the procedure.
4. Maximal medical therapy:
 - a) Oral antibiotics of 2-4 weeks' duration for patients with CRS (chronic rhinosinusitis) (culture-directed if possible).
 - b) Oral antibiotics with multiple 1-3 week courses for patients with RARS (recurrent acute rhinosinusitis).
 - c) Systemic or topical steroids (discretion of physician).
 - d) Saline irrigation (optional).
 - e) Topical and/or systemic decongestants (optional).

RATIONALE

This policy was created in 2006 and updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period through January 3, 2019. The following is a summary of the key literature evidence to date.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function - including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality

and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The primary outcome measures relevant for the treatment of chronic rhinosinusitis (CRS) are patient-reported symptoms and quality of life. Studies should predefine responder criteria for whatever outcome measures are used and assess between-group differences in the proportion of patients considered responders. Examiner evaluation of the nasal and sinus appearance and polyp size may provide some information about treatment outcomes, but these evaluations are limited by the lack of universally accepted standards.

Balloon Ostial Dilation as a Stand-Alone or Adjunct Procedure

This section discusses both indications - balloon ostial dilation as a stand-alone and as an adjunct procedure - because the systematic reviews discuss both approaches or do not distinguish sufficiently between one and the other procedure.

Systematic Reviews

A 2012 TEC Assessment on balloon ostial dilation for treatment of CRS reviewed evidence from 1 RCT, 3 nonrandomized comparative studies, and 9 case series.⁴ The TEC Assessment concluded that the evidence was insufficient to determine the effect of the technology on health outcomes. One RCT comparing balloon sinus ostial dilation with FESS was inadequately powered and did not evaluate differences in outcomes between treatments. While most nonrandomized comparative studies of balloon sinus ostial dilation and FESS showed no difference in health outcomes between both treatments, confounding factors might have biased the comparisons. Several case series showed improvement in symptoms of rhinosinusitis over baseline measures, and such improvement appeared durable up to 2 years. Case series did not allow conclusions on the comparative efficacy of balloon sinus ostial dilation to FESS.

A Cochrane review (2011) assessed the literature on balloon sinus ostial dilation for CRS.⁵ Reviewers concentrated on RCTs, and included the Plaza et al (2011) RCT⁶ as the sole controlled trial meeting selection criteria. Reviewers rated this trial as having a low risk of bias for most parameters, but a high risk of bias in reporting outcomes. They noted that symptom scores were not presented systematically and that details of statistical testing were not reported. Reviewers' overall conclusion was that there is no convincing evidence supporting the use of balloon sinus ostial dilation in CRS.

Levy et al (2016) reported on a systematic review and meta-analysis of studies of paranasal balloon ostial dilation for CRS.⁷ Reviewers included 17 studies, with 3 RCTs (Achar et al [2012],⁸ Bikhazi et al [2014],⁹ Cutler et al [2013]¹⁰). Two RCTs reported on change score differences for the Sino-Nasal Outcome Test-20 (SNOT-20) between patients treated with balloon ostial dilation and with FESS (n=110; standard mean difference, -0.42; 95% confidence interval [CI], -1.39 to 0.55; $I^2=76%$). There were improvements in SNOT-20 scores and sinus opacification after balloon ostial dilation.

Batra et al (2011) performed a comprehensive review of the literature on balloon catheter technology in rhinology.¹¹ They included observational cohort studies that provided relatively less evidence about the efficacy of balloon ostial dilation. Reviewers concluded that prospective RCTs comparing FESS with balloon catheter technology were needed.

Section Summary: Balloon Ostial Dilation as a Stand-Alone or Adjunct Procedure

A number of systematic reviews that did not distinguish between balloon ostial dilation as a stand-alone or adjunct procedure were available. The evidence did not support the use of balloon ostial dilation in CRS or that there is a difference in outcomes between balloon ostial dilation and FESS.

Balloon Ostial Dilation as a Stand-Alone Procedure for Patients with Chronic Rhinosinusitis

Clinical Context and Test Purpose

The purpose of balloon ostial dilation as a stand-alone procedure is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as medical management and functional endoscopic sinus surgery, in patients with chronic rhinosinusitis.

The question addressed in this evidence review is: does balloon ostial dilation improve the net health outcome for patients with chronic rhinosinusitis?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with chronic rhinosinusitis, characterized by purulent nasal discharge, usually without fever, that persists for weeks to months.

Interventions

The therapy being considered is balloon ostial dilation as a stand-alone procedure.

Comparators

Comparators of interest include medical management (steroids, antibiotics, or decongestants) and functional endoscopic sinus surgery.

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity. To quantify the severity of CRS and to assess treatment response, various outcomes measures can be used, including radiologic scores, endoscopic grading, and patient-reported quality of life (QOL) measures. The SNOT-20 is a validated quality-of-life (QOL) outcome measure specifically for patients with rhinosinusitis. Patients rate the severity of 20 different symptoms on a scale of 0 (no problem) to 5 (problem as bad as it can be). The 20 symptoms can be further analyzed using four validated subscales: rhinologic symptoms, ear/face symptoms, sleep function, and psychological issues. A decrease of 0.8 of the mean SNOT-20 score is considered a clinically meaningful improvement in symptom improvement.

Timing

The existing literature evaluating balloon ostial dilation as a stand-alone procedure for treatment for chronic rhinosinusitis has varying lengths of follow up, ranging from 6 months to 1 year. While studies described below all reported at least one outcome of interest, longer follow-up was

necessary to fully observe outcomes. Therefore, 6 months to 1 year of follow-up is considered necessary to demonstrate efficacy.

Setting

Patients with chronic rhinosinusitis are managed by otolaryngologists and primary care providers in an outpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

REMODEL Trial

REMODEL was an industry-sponsored RCT (Cutler et al [2013]) that compared balloon ostial dilation as a stand-alone procedure with FESS.¹⁰ A total of 105 patients with recurrent acute sinusitis or chronic sinusitis and failure of medical therapy were randomized to balloon ostial dilation or FESS. Balloon ostial dilation was performed with the Entellus device, which is labeled for a transantral approach. FESS consisted of maxillary antrostomy and uncinectomy with or without anterior ethmoidectomy. Thirteen patients withdrew consent before treatment, 11 (21%) in the FESS group and 2 (4%) in the balloon ostial dilation group. The primary outcomes were the change in SNOT-20 scores at 6-month follow-up and mean number of postoperative debridements. Secondary outcomes included recovery time, complication rates, and rates of revision surgery. Noninferiority analysis was performed for the primary outcome of change in symptom score and superiority analyses was performed on the debridement outcome.

Ninety-one patients were available at 6-month follow-up. The improvement in the mean SNOT-20 score was 1.67 (1.10) in the balloon dilation group and 1.60 (0.96) in the FESS arm ($p=0.001$) for noninferiority. Postoperative debridements were more likely in the FESS group with a mean of 1.2 (1.0) compared to a mean of 0.1(0.6) in the balloon dilation group ($p<0.001$) for superiority in the balloon arm). Patients in the balloon dilation arm returned to normal daily activities faster (1.6 days vs 4.8 days, $p=0.002$ for superiority) and required fewer days of prescription pain medications (0.9 days vs 2.8 days, $p=0.002$ for superiority) with balloon dilation. There were no major complications in either group, and 1 patient in each group required revision surgery.

Bikhazi et al (2014) reported 1-year follow-up from the REMODEL trial.⁹ Eighty-nine (96.7%) subjects were available at 1 year. Improvement in the mean SNOT-20 score was 1.64 in the balloon dilation arm and 1.65 in the FESS arm ($p<0.001$ for noninferiority). During the year postprocedure, both groups had fewer self-reported rhinosinusitis episodes (mean reduction in episodes, 4.2 in the balloon arm vs 3.5 in the FESS arm; $p<0.001$).

Chandra et al (2016) reported on results up to 2 years postprocedure for subjects in the REMODEL trial, along with an additional 30 subjects treated with FESS or in-office balloon sinus dilation, for a reported total of 61 FESS patients and 74 balloon sinus dilation patients.¹² Follow-up data were available for 130, 66, and 25 patients at 12, 18, and 24 months, respectively. Details about group-specific treatment received and loss to follow-up were not reported for the additional 30 patients not included in the REMODEL trial. The balloon sinus dilation group required 0.2 debridements per patient compared with 1.0 per patient in the FESS group ($p<0.001$). Mean change in SNOT-20 score from baseline to 12-month follow-up was -1.59 ($p<0.001$) and -1.60 ($p<0.001$) for the balloon sinus dilation and FESS groups, respectively, which was considered clinically significant. These changes were maintained at 24 months. At 18 months, overall revision rates were 2.7% in the balloon dilation group and 6.9% in the FESS group.

In addition to the longer term results of the REMODEL trial, this article included a meta-analysis of the REMODEL balloon dilation-treated patients and data from 5 manufacturer-sponsored trials, three of which had previously been reported in peer-reviewed form (BREATHE: Stankiewicz et al [2010],¹³ Stankiewicz et al [2012]¹⁴; RELIEF: Levine et al [2013]¹⁵; XprESS Transnasal Maxillary Multi-Sinus: Gould et al [2014]¹⁶). Across the 6 studies, 358 patients (846 sinuses) were treated with balloon sinus dilation, including 121 not described in prior publications. In a random-effects model, overall mean and subscale scores for the SNOT-20 improved compared with baseline at every follow-up time point.

Table 2. Summary of Key RCT Characteristics: Stand Alone Balloon Ostial Dilation

Study; Trial	Countries	Sites	Dates	Participants ¹	Interventions	
					Active	Comparator
Cutler (2013); REMODEL -6 month ^{a10}	US	10	2011-2012	Adults with chronic sinusitis	Balloon dilation (n=52)	FESS (n=53)
Bikhazi (2014); ⁹ REMODEL-1 year	US	10	2011-2012	Adults with chronic sinusitis	Balloon dilation (n=50)	FESS (n=42)
Chandra (2016); ¹² REMODEL-2 year	US	38	NR	Adults with chronic sinusitis	Balloon dilation (n=74) ²	FESS (n=61) ²

FESS: functional endoscopic sinus surgery; RCT: randomized controlled trial; REMODEL: randomized evaluation of maxillary antrostomy versus ostial dilation efficacy through long-term follow-up; NR: not reported.

^a Industry supported

¹ Chronic sinusitis defined as sinusitis >12 weeks duration despite optimal medical therapy or recurrent acute sinusitis 4 episodes in 1 year.

² The 2- year follow-up cohort included the addition of 30 subjects treated with FESS or in-office balloon sinus dilation.

Table 3. Summary of Key RCT Results: Stand Alone Balloon Ostial Dilation

Study	Change in SNOT-20 Scores at 6 mo.	Mean Number of Postoperative Débridements	Change in SNOT-20 Scores at 1 yr.	Overall Revision Rates at 18 mo.
Cutler (2013); ¹⁰ REMODEL				
Balloon dilation	1.67	1.2		
FESS	1.60	0.1		
P-value	0.001	<0.001		
Bikhazi (2014); ⁹ REMODEL				
Balloon dilation			1.64	
FESS			1.65	
P-value			<0.001	

Study	Change in SNOT-20 Scores at 6 mo.	Mean Number of Postoperative Débridements	Change in SNOT-20 Scores at 1 yr.	Overall Revision Rates at 18 mo.
Chandra (2016); ¹² , REMODEL				
Balloon dilation				2.7%
FESS				6.9%

RCT: randomized controlled trial.

Table 4. Relevance Gaps

Study	Population ^a	Intervention ^b	Comparator ^c	Outcomes ^d	Follow-Up ^e
Cutler (2013); REMODEL					
Bikhazi (2014); REMODEL					
Chandra (2016); REMODEL	3. Source and characteristics of patients added to the study for final results was unclear	1. Randomization of added patients occurred outside of key study			

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

^b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

^c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

^d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

^e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Study Design and Conduct Gaps

Study	Allocation ^a	Blinding ^b	Selective Reporting ^c	Follow-Up ^d	Power ^e	Statistical ^f
Cutler (2013); REMODEL		1. Patients were not blinded to treatment 3. Postoperative medication not controlled and used by judgment of clinician		1. Differential loss post-randomization between study arms		
Bikhazi (2014); REMODEL		1. Patients were not blinded to treatment				
Chandra (2016); REMODEL		1. Patients were not blinded to treatment				

The evidence gaps stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

^a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

^b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

^c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

^d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

^e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

^f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Additional RCTs

Minni et al (2018) published a prospective, randomized study comparing balloon catheter dilation (BCD) and traditional endoscopic sinus surgery (ESS) as treatments for chronic rhinosinusitis of the frontal sinuses.¹⁷ At three Italian hospitals, 102 individuals (148 sinuses) were enrolled with mild involvement of the frontal sinus, the average post-procedure SNOT-20 scores for the BCD and ESS groups were 24.6 and 27.54 ($p=0.42$), respectively; for patients with moderate/severe involvement, the scores were 23.47 and 30.71 ($p<0.05$), respectively. Post-procedure Lund-Mackay scores were 0.58 (BCD) and 0.54 (ESS; $p=0.30$) in the mild group and 0.53 (BCD) and 0.78 (ESS; $p=0.38$) in the moderate/severe group. No limitations to the study were reported.

Bizaki et al (2014) reported on results from an RCT that compared balloon ostial dilation with FESS among patients with symptomatic chronic or recurrent rhinosinusitis.¹⁸ The trial enrolled 46 subjects, 4 of whom withdrew; the analysis included 42 patients ($n=21$ in each group; statistical power calculations reported). Both groups demonstrated significant improvements in SNOT-22 scores from baseline to postprocedure. There were no differences in change in total SNOT-22 scores between groups at 3 months postprocedure. As a 2016 follow-up publication, trialists reported on nasal airway resistance and sinus symptoms between FESS- and balloon ostial dilation-treated groups.¹⁹ For this analysis, 62 patients were included (32 from the FESS group, 30 from the balloon dilation group). Patients in the balloon ostial dilation group had significant improvements in nasal volume from pre- to postoperative measurements, but there were no significant differences between groups pre- or postoperatively in nasal volume.

Bizaki et al (2016) compared balloon ostial dilation with FESS, with a focus on mucociliary clearance.²⁰ While conducted at the same institution as the previously reported Bizaki RCT, this RCT did not specify whether it was conducted in the same set of patients. This trial enrolled 36 patients who were randomized to balloon ostial dilation ($n=17$) or to FESS ($n=19$); 7 patients dropped out (3 in the FESS group, 4 in the balloon dilation group) and were not included in analyses. SNOT-22 scores improved in both groups from pre- to postoperative analyses. However, changes in total SNOT-22 scores did not differ significantly between groups. There were no significant changes in mucociliary clearance before and after either treatment nor was there a significant between-group difference in mucociliary clearance.

Marzetti et al (2014) reported on results from a small RCT that compared balloon ostial dilation using an unspecified device (or devices) with FESS in the treatment of a sinus headache.²¹ The trial included 83 patients with a sinus headache, based on American Academy of Otolaryngology – Head and Neck Surgery definitions, 40 randomized to conventional endoscopic sinus surgery and 35 to balloon ostial dilation. In the balloon dilation group, 23 patients were “only frontal sinus balloon” patients, in which balloon catheters were the only tools used for frontal sinus sinusotomy, and 12 were “hybrid,” in which balloon catheters and traditional ESS were used concurrently. It was not specified how patients were selected for these groups. At 6-month follow-up, SNOT-22 scores improved from 28.6 (baseline) to 7.8 in the endoscopic sinus surgery group and from 27.3 (baseline) to 5.3 in the balloon dilation group; improvements in both groups were statistically significant ($p<0.001$).

An RCT from Turkey (2011) reported on physiologic outcomes.²² Twenty patients were randomized to removal of the uncinata process via FESS or to balloon sinus ostial dilation as a stand-alone procedure. The main outcome measures were CO₂ concentration in the sinuses and maximum sinus pressure, both intended as surrogate measures for sinus ventilation. The CO₂ concentration decreased in both study arms to a similar degree. The maximum sinus pressure decreased in the FESS group but did not change in the balloon sinus ostial dilation group.

Another RCT, published by Achar et al (2012), enrolled 24 patients with CRS who had failed medical therapy and were scheduled for surgery.⁸ Patients were randomized to balloon dilation or to FESS and followed for 24 weeks. The primary outcome measures were changes in SNOT-20 scores and clearance time using the saccharin test. Both groups improved significantly on both measures. The degree of improvement was greater for the balloon dilatation group than for the FESS group on both the SNOT-20 score (43.8 vs 29.7, $p < 0.03$) and on the saccharin test score (7.5 vs 3.5, $p = 0.03$). Adverse events were not reported.

Bozdemir et al (2011) published a small study of 10 patients with nasal polyposis, in which 1 nasal passage was treated with FESS and the other with balloon sinus ostial dilation.²³ All procedures were performed by the same surgeon, and polypectomy was performed before FESS or balloon sinus ostial dilation in all patients. Outcome measures included sinus patency, as measured by computed tomography (CT) scan (Lund-Mackay classification) or repeat endoscopy (Mackay grading). At 10 days postprocedure, there were improvements in both groups on measures of patency, but no differences between groups.

Single-Arm Studies

Some single-arm studies have reported follow-up beyond 2 years for balloon ostial dilation and are described here. Bolger et al (2007) reported on outcomes at 24 weeks from a prospective, multicenter study of balloon sinus ostial dilation.²⁴ In this study, 115 patients, for whom FESS was recommended, received treatment with the balloon catheter. Sinusotomy was attempted in 358 sinuses, and cannulation was successful in 347. Ostia patency rates were assessed at weeks 1, 12, and 24; at 24 weeks, 304 (88%) of the 347 sinuses were evaluated. While only five were nonpatent, the status of 18% was reported as indeterminate. Patients' symptoms as measured by SNOT-20 scores also improved posttreatment. The device malfunctioned in 12 (3.4%) of 358 cases, the balloon ruptured in 7 cases, and the catheter tip malfunctioned in 4 cases. The authors indicated that there were no serious adverse events.

The additional follow-up to 2 years has been reported for a subset of the 115 patients in the previous study.^{25,26} At the 1-year follow-up, 70 (61%) of the 115 patients remained in the study.²⁵ Of the 66 patients who had follow-up nasal endoscopy, 85% of sinus ostia were patent; however, by adding results of CT scans showing improvement, 92% were judged to have functional patency. The report on clinical symptoms at 2-year follow-up involved a similar subset of patients (N=65).²⁶ In this longer term study, in which 34 patients had only balloon treatment, 85% of patients had improved symptoms. Revision treatment was required in 3.6% of sinuses involving 6 (9%) of 65 patients.

A second prospective multicenter, single-arm study of balloon sinus ostial dilation in refractory rhinosinusitis was published by Stankiewicz et al (2010).¹³ They reported 1-year follow-up data of the Balloon Remodeling Antrostomy Therapy (BREATHE I) study. In it, 30 patients received balloon dilation of the ethmoid infundibulum using the FinESS system, a transantral dilation approach via

the canine fossa. The primary outcome measure was patient-reported quality of life measured using the SNOT-20. Average overall symptom score at baseline was 2.9. At 3, 6, and 12 months postintervention, average overall symptom scores were 0.7, 0.8, and 0.8, respectively.

Two-year results from the BREATHE study were reported in 2012.¹⁴ At that time, 59 patients were treated with balloon sinus ostial dilation, with a mean follow-up of 27 months. Mean SNOT-20 scores improved from 2.65 at baseline to 0.79 at the longest follow-up. This report also discussed measures of functional impairment using the Work Limitation Questionnaire and the Work Productivity and Activity Impairment Questionnaire. Mean scores on the Work Limitation Questionnaire for overall productivity loss decreased from 8% at baseline to 2.5% at longest follow-up (estimates from graphical representation), and this pre- and postchange was statistically significant ($p < 0.001$). Similar improvements were reported on other parameters of the Work Limitation Questionnaire and Work Activity Impairment Questionnaire.

Series with shorter follow-up have also been published. For example, Soler et al (2017) reported results of a single-arm study evaluating stand-alone balloon sinus dilation for CRS in children ages 2 to 21 years.²⁷ At 6-month follow-up, results of the Sinus and Nasal Quality of Life Survey were significantly improved compared with baseline ($p < 0.001$).

Section Summary: Balloon Ostial Dilation as a Stand-Alone Procedure for Patients with Chronic Rhinosinusitis

One randomized comparative trial of balloon ostial dilation as a stand alone procedure compared with FESS with follow-up beyond the immediate postoperative period has been reported. This RCT, the REMODEL trial (105 patients randomized), was likely to have adequate power to detect group differences for the treatment of chronic maxillary sinusitis. Short-term outcomes up through 18 months with balloon ostial dilation are similar to those with FESS. Noninferiority for the mean improvement in SNOT-20 scores and superiority for balloon ostial dilation for postoperative debridement rates were demonstrated. The trial had methodologic limitations, including lack of blinded outcome assessment and differential post-randomization pretreatment dropout rates. Interpretation of the 2-year follow-up final results of the REMODEL trial was limited by the addition of patients from other sources where the reporting on randomization, timing of intervention and follow-up duration was incomplete. A group of small RCTs have compared balloon ostial dilation to FESS for treatment of other sinus locations and which have evaluated other outcomes such as sinus patency. Several single-arm studies are available for balloon ostial dilation as a stand-alone or adjunct procedure for individuals with chronic rhinosinusitis. These studies found significant improvements in symptoms and patients' quality of life.

Balloon Ostial Dilation as an Adjunct to FESS for Patients with Chronic Rhinosinusitis Clinical Context and Test Purpose

The purpose of balloon ostial dilation as an adjunct to functional endoscopic sinus surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as functional endoscopic sinus surgery alone, in patients with chronic rhinosinusitis.

The question addressed in this evidence review is: does balloon ostial dilation improves the net health outcome for patients with chronic rhinosinusitis?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest are individuals with chronic rhinosinusitis.

Interventions

The therapy being considered is balloon ostial dilation as an adjunct to functional endoscopic sinus surgery.

Comparators

Comparators of interest include functional endoscopic sinus surgery alone. Patients may also receive concomitant medical therapy with steroids, antibiotics, or decongestants.

Outcomes

The general outcomes of interest are symptoms, change in disease status, quality of life, and treatment-related morbidity.

Timing

The existing literature evaluating balloon ostial dilation as an adjunct to functional endoscopic sinus surgery as a treatment for chronic rhinosinusitis has varying lengths of follow up, ranging from 6 months to 1 year. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 6 months to 1 year of follow-up is considered necessary to demonstrate efficacy.

Setting

Patients with chronic rhinosinusitis are managed by otolaryngologists and primary care providers in an inpatient clinical setting.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Randomized Controlled Trials

Two RCTs identified have evaluated the incremental benefit of balloon ostial dilation plus FESS compared with FESS alone.

Hathorn et al (2015) reported on results of a single-blinded, randomized trial of balloon dilation with the Ventera Sinus Dilation System as an adjunct to frontal sinusotomy (Draf IIA) in which each patient served as his or her own control.²⁸ The Draf IIA procedure involves a more extensive drainage procedure with resection of the floor of the frontal sinus. Thirty patients with CRS were randomized to the right or left balloon sinus dilation in conjunction with frontal sinusotomy. Both groups had high (30/30) rates of sinus ostia patency at 3 months postprocedure. Several procedure-related factors differed between groups: the hybrid (balloon sinuplasty) procedures

were significantly shorter (655 seconds vs 898 seconds; 95% CI for difference, 30.9 to 454.4 seconds; $p=0.03$) and associated with less estimated blood loss (53 mL vs 91 mL; 95% CI for difference, 8.8 to 57.5 mL; $p=0.008$).

A double-blinded RCT of balloon sinus ostial dilation as an adjunct to FESS vs FESS alone was published by Plaza et al (2011).⁶ This trial enrolled 34 patients with CRS who were refractory to intensive medical management. Patients were randomized to a “hybrid approach” that included balloon sinus ostial dilation of the affected frontal recess along with traditional FESS of other paranasal sinuses, or to traditional FESS with the Draf I procedure. In both groups, an anterior ethmoidectomy was performed. A posterior ethmoidectomy and/or sphenoidotomy were performed as required by intraoperative assessment in both groups. Outcome measures at 12-month follow-up included symptoms, the Rhinosinusitis Disability Index, CT results of sinus patency, and the permeability of the frontal recess, as assessed by office endoscopy. One dropout was reported in each group, leaving 16 patients per group for analysis. For both groups, there were improvements in symptoms, standardized rhinosinusitis scoring indices, and CT patency, but no differences between groups. Rates for the 12-month outcome of endoscopic patency were 73% in balloon sinus ostial dilation patients and 63% in FESS patients. The published trial contained contradictory statements on whether this difference was statistically significant. The lead trialist clarified that the difference reported in the results for endoscopic patency was not statistically significant (G. Plaza, personal communication, April 2012). There were no major complications reported.

Section Summary: Balloon Ostial Dilation as an Adjunct to FESS for Patients with Chronic Rhinosinusitis

Two RCTs evaluating balloon ostial dilation as an adjunct to FESS were identified. Both suggested that the addition of balloon ostial dilation to traditional procedures can be done without adverse effects. One trial reported improved procedure times and less blood loss with balloon ostial dilation, although it is not clear whether the procedure time and blood loss were evaluated by a blinded observer. Both trials reported no significant differences between the hybrid and standard approaches in terms of sinus ostia patency.

SUMMARY OF EVIDENCE

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as a stand-alone procedure, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available systematic reviews (including a Cochrane review and a TEC Assessment) concluded that, although nonrandomized evidence has suggested balloon ostial dilation has similar outcomes to FESS, evidence from randomized trials is needed to demonstrate an improvement in outcomes for patients treated with balloon ostial dilation. Since the publication of those systematic reviews, the REMODEL RCT has been published. It assessed 105 patients, reporting comparable symptom improvement from 6 months through 18 months in patients with chronic maxillary sinusitis who received balloon ostial dilation or FESS. Lower rates of postoperative debridement to remove clots and scar tissue were found in the balloon treated patients. Balloon ostial dilation can be performed with local anesthesia in the office setting. Limitations of the REMODEL trial included its unblinded outcomes assessment and differential dropout between groups. Other trials have provided limited additional evidence. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic rhinosinusitis who receive balloon ostial dilation as an adjunct to FESS, the evidence includes 2 RCTs and single-arm series. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Neither available RCT reported significant clinically meaningful benefits associated with the addition of balloon ostial dilation to FESS. The evidence is insufficient to determine the effects of the technology on health outcomes.

CLINICAL INPUT RECEIVED THROUGH PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2013 Input

In response to requests, input was received from 2 specialty societies and 6 academic medical centers while this policy was under review in 2013. The overall input was mixed on whether balloon ostial dilation should be medically necessary, either as a stand-alone procedure or as an adjunct to FESS. There was no consensus on subpopulations of patients with chronic rhinosinusitis who might benefit from balloon ostial dilation. There was consensus that RCTs should be performed comparing balloon ostial dilation with standard care in order to determine efficacy.

2011 Input

In response to requests, input was received from 2 physician specialty societies and 6 academic medical centers while this policy was under review in 2011. Input was mixed. A number of reviewers agreed that this technique was investigational. These reviewers commented about the need for additional trials to compare outcomes with standard approaches. Comments were made on the lack of selection criteria for use of the balloon catheter. Reviewers also noted that the current studies do not permit separating the results for use of the balloon from concurrent FESS, because most studies used both techniques.

2008 Input

In response to requests, input was received from 2 physician specialty societies and 2 academic medical centers while this policy was under review in 2008. Input from 1 specialty society did not specifically address the clinical aspects of this technique but made comments related to coding. Another specialty society noted concerns due to lack of controlled studies and also commented that the long-term objective follow-up (eg, computed tomography scans) was on a limited number of patients. Input from 2 academic centers indicated this treatment was not investigational but should be viewed as just another surgical tool for the treatment of chronic sinusitis.

PRACTICE GUIDELINES AND POSITION STATEMENTS

National Institute for Health and Care Excellence

A 2008 practice guideline on balloon catheter dilation of paranasal sinus ostia from the National Institute for Health and Clinical Evidence (UK) states: "Current evidence on the short-term efficacy of balloon catheter dilation of paranasal sinus ostia for chronic sinusitis is adequate and raises no major safety concerns. Therefore, this procedure can be used provided that normal arrangements are in place for clinical governance, consent and audit."²⁹ In 2016, NICE published a recommendation on the use of the XprESS Multi-Sinus Dilation System for the treatment of chronic rhinosinusitis³⁰:

- 1.1 "The case for adopting the XprESS multi-sinus dilation system for treating uncomplicated chronic sinusitis after medical treatment has failed is supported by the evidence. Treatment with XprESS leads to a rapid and sustained improvement in chronic symptoms, fewer acute episodes and improved quality of life which is comparable to functional endoscopic sinus surgery (FESS).
- 1.2 XprESS should be considered in patients with uncomplicated chronic sinusitis who do not have severe nasal polyposis. In these patients, XprESS works as well as FESS, is associated with faster recovery times, and can more often be done under local anaesthesia."

American Academy of Otolaryngology – Head and Neck Surgery

In 2017, the American Academy of Otolaryngology – Head and Neck Surgery updated its statement on balloon ostial dilation, reaffirming its 2010 position statement: "Sinus ostial dilation ... is a therapeutic option for selected patient with chronic rhinosinusitis.... This approach may be used alone ... or in conjunction with other instruments...."³¹

In 2015, the Academy’s Foundation updated its 2007 clinical practice guidelines on adult sinusitis, which do not discuss surgical therapy or use of balloon sinuplasty.³²

American Rhinologic Society

A position statement, revised in 2017, from the American Rhinologic Society, stated that sinus ostial dilation is "a therapeutic option for selected patients with chronic rhinosinusitis (CRS) ... who have failed appropriate medical therapy."³³

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 10.

Table 10. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT01990820	Study for the Management of Pediatric Chronic Rhinosinusitis With or Without Balloon Sinuplasty	25	Sept 2016 (completed)
NCT01714687 ^a	Comparison of Balloon Sinuplasty In-Office Versus Medical Management for Recurrent Acute Sinusitis Patients (CABERNET)	59	Apr 2016 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

31295	Nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (eg, balloon dilation), transnasal or via canine fossa
31296	Nasal/sinus endoscopy, surgical; with dilation of frontal sinus ostium (eg, balloon dilation)
31297	Nasal/sinus endoscopy, surgical; with dilation of sphenoid sinus ostium (eg, balloon dilation)
31298	Nasal/sinus endoscopy, surgical; with dilation of frontal and sphenoid sinus ostia (eg, balloon dilation)
31299	Unlisted procedure, accessory sinuses
C1726	Catheter, balloon dilation, nonvascular

- Prior to 2011, and perhaps in the future, this procedure might be coded as an unlisted sinus procedure (31299). It could be submitted alone or along with other nasal/sinus endoscopy codes.

ICD-10 Diagnoses

J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis

REVISIONS

02-16-2011	Description Section updated. Rationale Section updated. References Section updated. In Coding section: <ul style="list-style-type: none"> ▪ Added CPT codes: 31295, 31296, 31297.
08-01-2011	In the Policy section: Liberalized the medical policy language from "Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of sinusitis is considered experimental / investigational." to "Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to endoscopic sinus surgery." In the Rationale section: <ul style="list-style-type: none"> ▪ In the summary section, removed the second paragraph, "In addition, more information is needed to determine which patients and which sinuses might be treated with the balloon technique and which require standard approaches. Given the limitations of the available data, the uncertain impact on clinical outcomes and questions about which patients might be candidates for this procedure, this approach is considered investigational." Added Policy Guidelines section.
09-21-2011	In the Policy Guidelines section: <ul style="list-style-type: none"> ▪ Added the new Item #2, "Beginning in 2011, there are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus

	<p>site." This statement was moved from the Coding section to the Policy Guidelines section.</p> <ul style="list-style-type: none"> Removed from the new Item #3, "Plans should be aware of this possibility." <p>In the Coding section: removed S2344 (deleted 04/01/11).</p>
09-24-2012	<p>Description section updated.</p> <p>Rationale section updated.</p> <p>Reference section updated.</p>
11-11-2016	<p>Updated Description section.</p> <p>In Policy section:</p> <ul style="list-style-type: none"> Removed "Use of a catheter-based inflatable device (balloon sinuplasty) in the treatment of medically refractory chronic sinusitis may be considered medically necessary as a minimally invasive alternative to endoscopic sinus surgery." Replaced with the following: "A. Balloon sinus ostial dilation is considered medically necessary for treating rhinosinusitis lasting longer than 12 weeks or 4 or more documented episodes of acute rhinosinusitis (in one year) <u>when all of the following are met</u>: 1. Confirmation with computed tomography (CT) scan and/or nasal endoscopy of findings of rhinosinusitis that includes <u>one or more of the following</u>: a) Nasal endoscopy showing purulent discharge or persistent inflammatory sinus pathology, OR b) CT evidence of mucosal thickening, bony remodeling, bony thickening, or obstruction of the ostiomeatal complex; AND 2. Balloon sinus ostial dilation is limited to the frontal, maxillary or sphenoid sinuses; AND 3. Balloon sinus ostial dilation is performed either as a stand-alone procedure or as part of functional endoscopic sinus surgery (FESS); AND 4. Balloon sinus ostial dilation is performed on patients whose symptoms persist despite maximal medical therapy (see Policy Guidelines). B. Balloon ostial dilation is considered not medically necessary in the following situations: 1. Nasal polyposis (Grade 2 or greater). 2. Samter's triad (aspirin sensitivity). 3. Severe sinusitis secondary to autoimmune or connective tissue disorders (i.e., including, but not limited to, sarcoidosis, Wegener's granulomatosis). 4. Severe sinusitis secondary to ciliary dysfunction, including, but not limited to, cystic fibrosis. 5. Contraindication to, or inability to tolerate local and/or topical anesthetic. 6. History of failed balloon procedure in the sinus to be treated. 7. Sinusitis with extensive fungal disease 8. Isolated ethmoid sinus disease. 9. Significant neo-osteogenesis. C. Balloon sinus ostial dilation for treatment of chronic sinusitis is considered experimental / investigational for all other indications." <p>In Policy Guidelines:</p> <ul style="list-style-type: none"> In Item 1, removed, "Beginning in 2011, t" and added "T" to read "There are specific category I CPT codes for these procedures (31295-31297). These codes may be used to describe balloon sinuplasty when no other surgical intervention has been performed on the same sinus site." Added Item 4, "Maximal medical therapy: a)Oral antibiotics of 2-4 weeks' duration for patients with CRS (chronic rhinosinusitis) (culture-directed if possible. b) Oral antibiotics with multiple 1-3 week courses for patients with RARS (recurrent acute rhinosinusitis). c) Systemic or topical steroids (discretion of physician). d) Saline irrigation (optional). e) Topical and/or systemic decongestants (optional). <p>Updated Rationale section.</p> <p>Updated References section.</p>
07-01-2017	<p>Updated Description section.</p> <p>Updated Rationale section.</p> <p>Updated References section.</p>
01-01-2018	<p>In Coding section:</p> <ul style="list-style-type: none"> Added CPT code: 31298. Removed ICD-9 codes.
03-14-2018	<p>Updated Description section.</p>

	Updated Rationale section.
03-27-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.

REFERENCES

1. Hopkins C, Browne JP, Slack R, et al. The Lund-Mackay staging system for chronic rhinosinusitis: how is it used and what does it predict? *Otolaryngol Head Neck Surg.* Oct 2007;137(4):555-561. PMID 17903570
2. Lund VJ, Kennedy DW. Staging for rhinosinusitis. *Otolaryngol Head Neck Surg.* Sep 1997;117(3 Pt 2):S35-40. PMID 9334786
3. Hopkins C, Gillett S, Slack R, et al. Psychometric validity of the 22-item Sinonasal Outcome Test. *Clin Otolaryngol.* Oct 2009;34(5):447-454. PMID 19793277
4. Blue Cross and Blue Shield Association Technology Evaluation Center Program. Balloon Ostial Dilation for Treatment of Chronic Rhinosinusitis. *TEC Assessments 2012*;27:Tab 9. PMID
5. Ahmed J, Pal S, Hopkins C, et al. Functional endoscopic balloon dilation of sinus ostia for chronic rhinosinusitis. *Cochrane Database Syst Rev.* Jul 6 2011(7):CD008515. PMID 21735433
6. Plaza G, Eisenberg G, Montojo J, et al. Balloon dilation of the frontal recess: a randomized clinical trial. *Ann Otol Rhinol Laryngol.* Aug 2011;120(8):511-518. PMID 21922974
7. Levy JM, Marino MJ, McCoul ED. Paranasal sinus balloon catheter dilation for treatment of chronic rhinosinusitis: a systematic review and meta-analysis. *Otolaryngol Head Neck Surg.* Jan 2016;154(1):33-40. PMID 26519456
8. Achar P, Duvvi S, Kumar BN. Endoscopic dilatation sinus surgery (FEDS) versus functional endoscopic sinus surgery (FESS) for treatment of chronic rhinosinusitis: a pilot study. *Acta Otorhinolaryngol Ital.* Oct 2012;32(5):314-319. PMID 23326011
9. Bikhazi N, Light J, Truitt T, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: A prospective, multicenter, randomized, controlled trial with 1-year follow-up. *Am J Rhinol Allergy.* Jul 2014;28(4):323-329. PMID 24823902
10. Cutler J, Bikhazi N, Light J, et al. Standalone balloon dilation versus sinus surgery for chronic rhinosinusitis: a prospective, multicenter, randomized, controlled trial. *Am J Rhinol Allergy.* Sep-Oct 2013;27(5):416-422. PMID 23920419
11. Batra PS, Ryan MW, Sindwani R, et al. Balloon catheter technology in rhinology: reviewing the evidence. *Laryngoscope.* Sep 7 2011;121(1):226-232. PMID 20824793
12. Chandra RK, Kern RC, Cutler JL, et al. REMODEL larger cohort with long-term outcomes and meta-analysis of standalone balloon dilation studies. *Laryngoscope.* Jan 2016;126(1):44-50. PMID 26228589
13. Stankiewicz J, Truitt T, Atkins J, Jr. One-year results: Transantral balloon dilation of the ethmoid infundibulum. *Ear Nose Throat J.* Feb 2010;89(2):72-77. PMID 20155675
14. Stankiewicz J, Truitt T, Atkins J, et al. Two-year results: transantral balloon dilation of the ethmoid infundibulum. *Int Forum Allergy Rhinol.* May-Jun 2012;2(3):199-206. PMID 22337530
15. Levine SB, Truitt T, Schwartz M, et al. In-office stand-alone balloon dilation of maxillary sinus ostia and ethmoid infundibula in adults with chronic or recurrent acute rhinosinusitis: a prospective, multi-institutional study with-1-year follow-up. *Ann Otol Rhinol Laryngol.* Nov 2013;122(11):665-671. PMID 24358625
16. Gould J, Alexander I, Tomkin E, et al. In-office, multisinus balloon dilation: 1-Year outcomes from a prospective, multicenter, open label trial. *Am J Rhinol Allergy.* Mar-Apr 2014;28(2):156-163. PMID 24598043
17. Minni A, Dragonetti A, Sciuto A, et al. Use of balloon catheter dilation vs. traditional endoscopic sinus surgery in management of light and severe chronic rhinosinusitis of the frontal sinus: a multicenter prospective randomized study. *Eur Rev Med Pharmacol Sci.* Jan 2018;22(2):285-293. PMID 29424885
18. Bizaki AJ, Taulu R, Numminen J, et al. Quality of life after endoscopic sinus surgery or balloon sinuplasty: a randomized clinical study. *Rhinology.* Dec 2014;52(4):300-305. PMID 25479206

19. Bizaki AJ, Numminen J, Taulu R, et al. Decrease of nasal airway resistance and alleviations of symptoms after balloon sinuplasty in patients with isolated chronic rhinosinusitis: a prospective, randomised clinical study. *Clin Otolaryngol*. Dec 2016;41(6):673-680. PMID 26548697
20. Bizaki AJ, Numminen J, Taulu R, et al. A controlled, randomized clinical study on the impact of treatment on antral mucociliary clearance: uncinectomy versus balloon sinuplasty. *Ann Otol Rhinol Laryngol*. May 2016;125(5):408-414. PMID 26611244
21. Marzetti A, Tedaldi M, Passali FM. The role of balloon sinuplasty in the treatment of sinus headache. *Otolaryngol Pol*. Jan-Feb 2014;68(1):15-19. PMID 24484944
22. Kutluhan A, Salviz M, Bozdemir K, et al. The effects of uncinectomy and natural ostial dilatation on maxillary sinus ventilation: a clinical experimental study. *Eur Arch Otorhinolaryngol*. Apr 2011;268(4):569-573. PMID 21110035
23. Bozdemir K, Kutluhan A, Cetin H, et al. Comparison of outcomes of simple polypectomy plus balloon catheter dilatation versus functional endoscopic sinus surgery in nasal polyposis: a preliminary study. *Am J Rhinol Allergy*. May-Jun 2011;25(3):198-200. PMID 21679533
24. Bolger WE, Brown CL, Church CA, et al. Safety and outcomes of balloon catheter sinusotomy: a multicenter 24-week analysis in 115 patients. *Otolaryngol Head Neck Surg*. Jul 2007;137(1):10-20. PMID 17599558
25. Kuhn FA, Church CA, Goldberg AN, et al. Balloon catheter sinusotomy: one-year follow-up--outcomes and role in functional endoscopic sinus surgery. *Otolaryngol Head Neck Surg*. Sep 2008;139(3 Suppl 3):S27-37. PMID 18707992
26. Weiss RL, Church CA, Kuhn FA, et al. Long-term outcome analysis of balloon catheter sinusotomy: two-year follow-up. *Otolaryngol Head Neck Surg*. Sep 2008;139(3 Suppl 3):S38-46. PMID 18707993
27. Soler ZM, Rosenbloom JS, Skarada D, et al. Prospective, multicenter evaluation of balloon sinus dilation for treatment of pediatric chronic rhinosinusitis. *Int Forum Allergy Rhinol*. Mar 2017;7(3):221-229. PMID 27888649
28. Hathorn IF, Pace-Asciak P, Habib AR, et al. Randomized controlled trial: hybrid technique using balloon dilation of the frontal sinus drainage pathway. *Int Forum Allergy Rhinol*. Feb 2015;5(2):167-173. PMID 25360863
29. National Institute of Health and Care Excellence (NICE). Balloon catheter dilation of paranasal sinus ostia for chronic sinusitis [IPG273]. 2008; <http://www.nice.org.uk/guidance/IPG273/chapter/1-Guidance>. Accessed January 23, 2019.
30. National Institute of Health and Care Excellence (NICE). XprESS multi sinus dilation system for treating chronic sinusitis [MTG30]. 2016; <https://www.nice.org.uk/guidance/mtg30>. Accessed January 23, 2019.
31. American Academy of Otolaryngology - Head and Neck Surgery. Position Statement: Dilation of sinuses, any method (e.g., balloon, etc.). 2017; <https://www.entnet.org/?q=node/542>. Accessed January 23, 2019.
32. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. *Otolaryngol Head Neck Surg*. Apr 2015;152(2 Suppl):S1-S39. PMID 25832968
33. American Rhinologic Society (ARS). Ostial Balloon Dilation Position Statement. 2017; https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=33:ostial-balloon-dilation-position-statement&catid=26:position-statements&Itemid=197. Accessed January 23, 2019.

Other References

1. Blue Cross and Blue Shield of Kansas Otolaryngology Liaison Committee, August 2010; August 2011; August 2014; July 2015; January 2016; May 2017.